

RISK ASSESSMENT AND SCIENCE SUPPORT BRANCH

ANTIMICROBIAL DIVISION

EFFICACY REVIEW - II

EPA Reg. No. or File Symbol 1677-RIL

EPA Petition or EUP No. None

Date Division Received 11-4-97

Type Product Hospital Disinfectant

MRID No(s) 44195801

Product Management Team PM 33

Product Name KX-6085

Company Name Ecolab

200.0 **Introduction:**

200.1 **Uses:**

Hospital Disinfectant

200.2 **Background Information:**

The registrant is submitting food contact surface sanitizer data; no label to review.

200.3 **Factors Affecting Amount/Type of Data Required:**

None

201.0 **Data Summary**

None

201.1 **Abstract of Test Reports:**

"Oxy-15 Food Contact Surface Sanitizing Efficacy" by Pamela Reed of Ecolab, Mendota heights, MN 55118, dated December 3, 1996. MRID No. 44195801.

None

201.2 **Brief Description of Tests:**

201.3 **Data Summaries**

None

201.4 **Other Summarized Results:**

See Recommendations under 202.0.

202.0 Recommendations

202.1 ACCEPTABLE Data

"Oxy-15 Food Contact Surface Sanitizing Efficacy" by Pamela Reed of Ecolab, Mendota heights, MN 55118, dated December 3, 1996. MRID No. 44195801.

The submitted efficacy data appear adequate to support effectiveness of the product as a food contact surface sanitizer against Staphylococcus aureus ATCC 6538 and Escherichia coli ATCC 11229 on hard, nonporous surfaces when diluted 1 oz per 10 gallon in 500 ppm AOAC hard after a contact time of 30 seconds at room temperature (25°C).

203.0 Labeling:

The proposed labeling is UNACCEPTABLE.

The registrant claims that the product 1677-RIL is substantially similar to two other Ecolab products, Oxy-15, EPA Reg. No. 1677-164 and Oxonia Active, EPA Reg. No. 1677-129. The registrant wants to use the claims appearing on EPA Reg. 1677-129.

The label for EPA Reg. 1677-129 show that although both products have the same active ingredients, they are not substantially similar. The registrant may use the claims on EPA Reg. No. 1677-164, since this product is substantially similar to EPA Reg. No. 1677-RIL.

<u>PRODUCT</u>	<u>HYDROGEN PEROXIDE</u>	<u>PEROXYACETIC ACID</u>	<u>INERTS</u>
*1677-RIL	11.2%	15.2%	73.6%
*1677-164	11.0%	15.0%	74.0%
1677-129	27.5%	5.8%	66.7%

Notice that in 1677-129, Hydrogen Peroxide is the main Active Ingredient and in 1677-RIL and 1677-164 it is the Peroxyacetic acid.

Also, the registrant must remove any food contact surface sanitizing claims against Listeria monocytogenes, Salmonella typhimurium, Pseudomonas aeruginosa, Saccharomyces cerevisiae, Vibrio cholerae, Pediococcus damnosus and Lactobacillus buchneri.

SUBJECT: PRODUCT CHEMISTRY REVIEW - Antimicrobial Division
DP Barcode D242045 Reg. No. or File Symbol 1677-RIL
Manufacturing-Use [] OR End-Use Product [✓]

TO: Marshall Swindell/Tony Kish
PM Team No. 33

FROM: Anna Skapars, Chemist
Risk Assessment and Science Support Branch

THRU: Norman Cook, Chief
Risk Assessment and Science Support Branch

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

Revised Confidential Statement of Formula dated 11-26-97 does not agree with the proposed updated label and CSF is not acceptable.

According to Confidential Statement of Formula dated 11-26-97 the ingredient statement in the label should declare

Hydrogen peroxide . . .	<u>11.2%</u>
Peroxyacetic acid . . .	<u>15.2%</u>

Submit revised correct Confidential Statement of Formula or revise ingredient statement in the label so that the declared percentages for the active ingredients will agree with CSF.

Note to PM:

Please verify dosage ratio with efficacy.

Anna Skapars
3-4-98